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| 10/523,474 | 09/06/2005 | Stefan Herz | 049202/286618 | 2299 |
| 826 | 7590 | 09/27/2007 | EXAMINER | |
| ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000 | | | KUBELIK, ANNE R | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,474

Applicant(s)

HERZ ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-15,18-20,23 and 24 is/are rejected.
- 7) ☒ Claim(s) 2,11,16 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-20 and 23-24 are pending.
2. The drawings filed 4 February 2005 are objected to because no details can be made out in Figs 3D, 12 and 13.
3. The abstract is not descriptive of the instantly claimed invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Sequence Rules

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from the sequences on pg 28, line 5; pg 29, lines 1 and 3; pg 30, lines 2 and 4; pg 31, lines 1-2; pg 32, lines 1-2; pg 33, line 6; pg 34, lines 1 and 3; and pg 37, line 2.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 6-8, 10, 12, 15 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

It is unclear in claim 3 what the first and second sequences of interest are different from.

It is unclear in claims 7-8 where the additional sequence of interest is located and how it is used in the claimed method, as there is no recitation of the sequence in claim 1

It is unclear in claims 7-8 if the gene of interest is the same thing as the sequence of interest in claim 1 or if it is an additional component of the DNA molecules.

Claim 6 lacks antecedent basis for the limitation "said one additional DNA molecule".

The process of claim 1 does not produce the seeds claimed in claim 24.

Claim 10 is indefinite in its recitation of "wherein expression of said gene of interest includes RNA trans-splicing". Recitation of "includes" makes it unclear if trans-splicing is actually involved.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1, 3-8, 12, 14-15, 18-20 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Herz et al (WO 02/055651).

Herz et al disclose a method of tobacco plastid transformation comprising introducing separately into plastids two DNA constructs. The first DNA construct comprises a first region homologous to the plastid genome (*trnL/ycf5*) and a first sequence of interest (an promoterless *aphA6* coding region operably linked to the *rbcl* 3' sequence) and the second DNA construct comprises a second region homologous to the plastid genome (*rpl32/sprA*), a promoter, a *uidA* sequence and a second sequence of interest (an *aphA6* coding region lacking a 3' sequence), wherein the first sequence of interest is homologous to at least a portion of said second sequence of interest and assembled upon integration as a continuous sequence that can be expressed (pg 19, ¶2, to pg 20, ¶1; pg 41, ¶2, to pg 43, ¶3; Fig. 20-22). Herz et al disclose selecting transformants with the two sequences of interest as a continuous sequence because *aph6* is a selectable marker (pg 19, ¶3; pg 42, ¶5). Additionally the first fragment of *aphA6* is The *rbcl* 3' sequence would be an additional sequence of interest on the first DNA construct, and the promoter and *uidA* sequence would be additional sequences of interest on the second DNA construct. An additional DNA molecule was introduced with the first DNA molecule; the additional DNA molecule encoded *aadA*, a sequence of interest conferring resistance to spectinomycin and streptomycin *aadA* (19, ¶2; pg 41, ¶2); the additional DNA molecule would contain sequence segments homologous the said first a second sequences of interest, wherein the sequence segments are at least two nucleotides long.. The first and second regions homologous to the plastid genome correspond to a continuous sequence of the tobacco plastid genome. The first and second DNA constructs would be a kit-of parts.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 3-9, 12-15, 18-20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herz et al (WO 02/055651).

The claims are drawn to a method of tobacco plastid transformation comprising introducing separately into plastids two DNA constructs, wherein the first construct comprises a first sequence of interest containing a 5' part of a gene of interest and the second construct comprises a second sequence of interest comprises the 3' part of the gene of interest. The claims are also drawn to the method wherein the first or second construct comprises a selectable marker gene outside the sequence of interest and a region homologous to a plastome region.

The teachings of Herz et al are discussed above. Herz et al do not disclose the first construct comprising the 5' part of a gene of interest and the second construct comprising the 3' part of the gene of interest.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of plastid transformation as taught by Herz et al, to change the order in which the portions of the gene of interest is introduced into the plastid or include the selectable marker for the first transformation on the first DNA construct. One of ordinary skill in the art would have been motivated to do the first because selection of having the 5' part of a gene of interest on the first DNA construct or the 3' part of the gene of interest on the first DNA

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construct is an obvious design choice. One of ordinary skill in the art would have been motivated to do the second because Herz et al teaches such an arrangement of selectable marker on the DNA construct in Fig. 12; using this over co-transformation with a second construct is an obvious design choice.

11. Claims 1, 3-10, 12-15, 18-20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herz et al (WO 02/055651) in view of Maliga et al (1995, US Patent 5,451,513).

The claims are drawn to a method of tobacco plastid transformation comprising introducing separately into plastids two DNA constructs, each comprising only a part of a gene of interest, wherein expression of the gene of interest involves trans-splicing.

The teachings of Herz et al are discussed above. Herz et al do not disclose the expression of the gene of interest including RNA trans-splicing.

Maliga et al teaches plastid DNA constructs in which expression of the gene of interest involves trans-splicing (column 19, line 59, to column 20, line 49).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of plastid transformation as taught by Herz et al, to have expression of the gene of interest involve trans-splicing as described in Maliga et al. One of ordinary skill in the art would have been motivated to do so because Maliga et al teaches that the trans-splicing system facilitates recovery of plastid transformants (column 20, lines 32-35).

12. Claims 16-17 are free of the prior art, given the failure of the prior art to teach or suggest a method of tobacco plastid transformation comprising introducing separately into plastids two

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DNA constructs, the first DNA construct comprising only one region homologous to the plastid genome and a first sequence of interest and the second DNA construct comprising a second region homologous to the plastid genome, a promoter and a second sequence of interest, wherein the first sequence of interest is homologous to at least a portion of said second sequence of interest and assembled upon integration as a continuous sequence that can be expressed. Claim 2 is free of the prior art, given the failure of the prior art to teach or suggest a method of tobacco plastid transformation comprising introducing separately into plastids two DNA constructs, the first DNA construct comprising a first region homologous to the plastid genome and a first sequence of interest and the second DNA construct comprising a second region homologous to the plastid genome, a promoter, a uidA sequence and a second sequence of interest, wherein DNA constructs are introduced by co-transformation. Claim 11 is free of the prior art, given the failure of the prior art to teach or suggest transforming plastids with two DNA constructs, wherein the constructs each comprise a portion of a sequence of interest and homologous regions outside the sequence of interests, wherein the homologous regions allow excision of the sequence of interest.

Claim Objections

13. Claim 2 objected to because there is a plurals disagreement in the phrase "molecule are" in line 2.

14. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. In claim 11 the parts of the gene of interest are excised; as a result the gene of interest cannot be expressed, as required by parent claim 9.

15. Claims 16-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claim 11 would be allowable if rewritten to overcome the objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

17. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if rewritten to overcome the objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

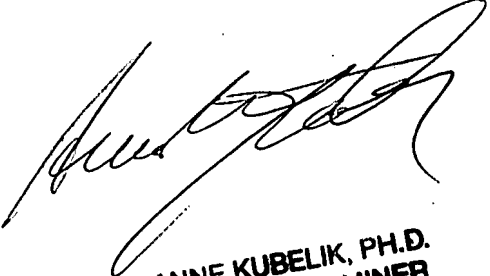
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Anne Kubelik, Ph.D.
September 13, 2007

A handwritten signature in black ink, appearing to read 'Anne Kubelik', written in a cursive style.

**ANNE KUBELIK, PH.D.
PRIMARY EXAMINER**